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**In the United States Patent and Trademark Office**

Appellants:	Rosann Marie Matthews Kaylor et al.	Docket No.:	16,976
Serial No.:	10/027,265	Group:	3736
Confirmation No:	3108	Examiner:	Jonathan M. Foreman
Filed:	December 21, 2001	Date:	February 20, 2007
For:	Method And Apparatus For Collecting And Testing Biological Samples		

**Brief on Appeal to the Board of Patent Appeals and Interferences**

Mail Stop Appeal Brief - Patents  
Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. 41.37 Appellants respectfully submit this Brief in support of their Appeal of Examiner Foreman's **Final Rejection** of claims 41, 43-46, 48-51, 53-58, and 75-79 which was mailed on February 22, 2006. And in response to Notification of Non-Compliant Appeal Brief which was mailed on January 25, 2007.

On June 22, 2006, Appellants, pursuant to 37 C.F.R. 41.31 mailed a Notice of Appeal along with a Petition For One Month Extension of Time. Thus, the time period for filing this Brief ended on August 27, 2006.

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**Real Party In Interest**

The present Application has been assigned to the Kimberly-Clark Worldwide, Inc.

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**Related Appeals and Interferences**

There are no related appeals and/or interferences.

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**Status of the Claims**

Claims 1-79 remain in the application with claims 41, 43-46, 48-51, 53-58, and 75-79 being finally rejected. Claims 1-40, 42, 47, 52, and 59-74 have been withdrawn.

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**Status of Amendments Filed Subsequent to Final Rejection**

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None.

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**Summary of the Invention For Each Independent Claim**

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Claim 41. Currently amended independent claim 41 is generally directed to a method for collecting a sample from a test subject, the method implicating a device that includes a generally tubular nonwoven body into which a finger is inserted to capture and retain a sample. (See, e.g., page 2, lines 16-23.)

Claim 46. Currently amended independent claim 46 is generally directed to a method for analyzing a sample in which a device that includes a generally tubular nonwoven body (into which a finger may be inserted) is used to contact a substance, and then the device is analyzed using a reader. (See, e.g., page 2, lines 16-23 and page 15, lines 19-34.)

Claim 51. Currently amended independent claim 51 is generally directed to a method for analyzing a sample in which a device that includes a generally tubular nonwoven body (into which a finger may be inserted) is used to contact a substance to be sampled, and then the reaction of the sample with an indicator agent on the device is observed. (See, e.g., page 2, lines 16-23 and page 15, lines 19-34.)

Claim 78. Currently amended independent claim 78 is generally directed to a method for collecting a sample from a test subject, the method implicating use of a finger glove device that includes a generally tubular body to capture and retain a sample. The finger glove device is made of a first panel comprising a non-elastic material containing a nonwoven web that is thermally bonded to a second panel comprising an elastic nonwoven material. The method's steps include providing the finger glove device, inserting a finger into the open end, and contacting the sample with the finger glove device. (See, e.g., page 2, lines 16-23; page 8, lines 2-6; page 8, lines 17-27; page 11, lines 6-9.)

Claim 79. Currently amended independent claim 79 is generally directed to a method for analyzing a sample, the method implicating use of a finger glove device that includes a generally tubular body to capture and retain a sample. The finger glove device is made of a first panel comprising a non-elastic material containing a nonwoven web that is attached to a second panel comprising an elastic nonwoven material. The method's steps including providing the finger glove device, inserting a finger into the open end, and contacting the sample with the finger glove device. (See, e.g., page 2, lines 16-23; page 8, lines 2-6; page 8, lines 17-27; page 11, lines 6-9.)

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**Statement of Each Ground of Rejection Presented For Review**

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1. **Rejection of Claims 41, 43, and 75 Under 35 U.S.C. §102(b).** In the Office Action mailed 22 February 2006, the Examiner rejected claims 41 and 43 as being unpatentable under 35 U.S.C. §102(b) over U.S. Patent No. 4,327,744 to Smith (hereinafter "the Smith patent").
2. **Rejection of Claims 41, 43-45, and 75 Under 35 U.S.C. §102(b).** In the Office Action mailed 22 February 2006, the Examiner rejected claims 41-45 as being unpatentable under 35 U.S.C. §102(b) over U.S. Patent No. 4,920,974 to Roth et al. (hereinafter "the Roth patent").
3. **Rejection of Claims 41, 43, 51, 53, 56, 57, 75, 77, and 79 Under 35 U.S.C. §102(b).** In the Office Action mailed 22 February 2006, the Examiner rejected claims 41, 43, 51, 53, 56, and 57 as being unpatentable under 35 U.S.C. §102(b) over U.S. Patent No. 6,123,676 to Anapliotis (hereinafter "the Anapliotis patent").
4. **Rejection of Claim 79 Under 35 U.S.C. §102(b).** In the Office Action mailed 22 February 2006, the Examiner rejected claim 79 as being unpatentable under 35 U.S.C. §102(b) over U.S. Patent No. 3,672,351 to Ubersax (hereinafter "the Ubersax patent").
5. **Rejection of Claim 78 Under 35 U.S.C. §102(b).** In the Office Action 22 February 2006, the Examiner rejected claim 78 as being unpatentable under 35 U.S.C. §102(b) over U.S. Patent No. 4,335,731 to Bora (hereinafter "the Bora patent").
6. **Rejection of Claims 41, 43, 46, 48 and 76 Under 35 U.S.C. §103(a).** In the Office Action mailed 22 February 2006, the Examiner rejected the preceding claims as unpatentable over U.S. Patent Application Publication Number 2004/0092843 to Kreiser et al. ("Kreiser") in view of U.S. Patent No. 5,728,340 to Dreibelbis et al. ("Dreibelbis").
7. **Rejection of Claims 44, 45, 54, and 55 as Obvious.** In the Office Action mailed 22 February 2006, the Examiner rejected claims 44, 45, 54, and 55 as being unpatentable under 35 U.S.C. §103(a) over the Anapliotis patent in view of U.S. Patent No. 6,114,024 to Forte ("the Forte patent").
8. **Rejection of Claims 49 and 50 as Obvious.** In the Office Action mailed 22 February 2006, the Examiner rejected the preceding claims as unpatentable over U.S. Patent Application Publication Number 2004/0092843 to Kreiser et al. ("Kreiser") in view of U.S. Patent No. 5,728,340 to Dreibelbis et al. ("Dreibelbis") and further in view of U.S. Patent No. 6,114,024 to Forte ("the Forte patent").
9. **Rejection of Claim 58 as Obvious.** In the Office Action mailed 22 February 2006, the Examiner rejects claim 58 as being unpatentable under 35 U.S.C. §103(a) over the Anapliotis patent in view of U.S. Patent No. 5,660,790 to Lawrence et al. ("the Lawrence patent"). Applicants respectfully traverse the rejection.

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**Argument**

**1. Remarks on Paragraphs 2-3 of the Office Action mailed on 22 February 2006: Rejection of Claims 41, 43, and 75 Under 35 U.S.C. §102(b)**

In the Office Action mailed 22 February 2006, the Examiner rejected claims 41, 43, and 75 as being unpatentable under 35 U.S.C. §102(b) over U.S. Patent No. 4,327,744 to Smith (hereinafter "the Smith patent").

The Examiner believes the Smith patent discloses the subject matter of claims 41, 43, and 75. Claim 41 as amended is directed to a method for collecting a sample from a test subject, the method including providing a device adapted to capture and retain the sample, wherein the device includes a generally tubular nonwoven body including a generally tubular inner surface defined by an interior layer, the inner surface defining a pocket therewithin, the pocket having a distal end and a proximal end, the distal end being generally closed and the proximal end being generally open, the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end, and a generally tubular outer surface; inserting a finger into the pocket; and contacting the sample with the device.

The Smith patent does not disclose the subject matter of the amended claims. The Examiner asserts that Smith discloses "a generally tubular elastic nonwoven," citing Col. 1, lines 50-52. (See Examiner's 22 February 2006 Final Office Action at page 2). A reader, directed to this citation, finds the following: "It is preferred that the finger member be constructed of an elastomeric material such as a silicone latex of the type used for surgical gloves." Nowhere does Smith recite a nonwoven body. (See present application at page 6, line 16 et seq., in which a nonwoven web is defined as "a web having a structure of individual fibers or threads that are interlaid, but not in an identifiable manner as in a knitted fabric.") A search of an electronic document corresponding to US, 4,327,744 found on the MicroPatents database for the term "nonwoven" was unsuccessful (i.e., using the "Find" feature, the term "nonwoven" was not found in the electronic document). Because Smith does not disclose each and every element of the claimed invention, it cannot anticipate.

In view of the remarks set forth in this section, Applicants respectfully submit that claims 41, 43, and 75 are in condition for allowance and respectfully request favorable consideration and the timely allowance of those claims.

**2. Remarks on Paragraph 4 of the Office Action mailed on 22 February 2006: Rejection of Claims 41, 43-45, and 75 Under 35 U.S.C. §102(b)**

In the Office Action mailed 22 February 2006, the Examiner rejects claims 41, 43-45, and 75 as being unpatentable under 35 U.S.C. §102(b) over U.S. Patent No. 4,920,974 to Roth et al. (hereinafter "the Roth patent").

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The Examiner believes the Roth patent discloses the subject matter of claims 41, 43-45, and 75. The Roth patent does not disclose the subject matter of the amended claims.

The Roth patent does not disclose the subject matter of the amended claims. The Examiner asserts that Roth discloses "a generally tubular elastic nonwoven," citing Col. 3, lines 13-16. (See Examiner's 22 February 2006 Final Office Action at page 3). A reader, directed to this citation, finds the following: "The sheath is typically fabricated from an inexpensive, water-impermeable rubbery material such as a natural rubber (latex) or a synthetic material such as polurethane or the like." Contrary to Examiner's assertion, the cited teaching emphasizes use of a "water-impermeabl rubbery material." Reading beyond Examiner's citation, one finds that an absorbent pad, such as cotton, is affixed to the sheath. But nowhere does Roth recite a nonwoven body. (See present application at page 6, line 16 et seq., in which a nonwoven web is defined as "a web having a structure of individual fibers or threads that are interlaid, but not in an identifiable manner as in a knitted fabric.") A search of an electronic document corresponding to US,4,920,974 found on the MicroPatents database for the term "nonwoven" was unsuccessful (i.e., using the "Find" feature, the term "nonwoven" was not found in the electronic document). Because Roth does not disclose each and every element of the claimed invention, it cannot anticipate.

In view of the remarks set forth in this section, Applicants respectfully submit that claims 41, 43-45, and 75 are in condition for allowance and respectfully request favorable consideration and the timely allowance of those claims.

**3. Remarks on Paragraph 5 of the Office Action mailed on 22 February 2006: Rejection of Claims 41, 43, 51, 53, 56, 57, 75, 77, 79 Under 35 U.S.C. §102(b)**

In the Office Action mailed 22 February 2006, the Examiner rejects claims 41, 43, 51, 53, 56, 57, 75, 77, and 79 as being unpatentable under 35 U.S.C. §102(b) over U.S. Patent No. 6,123,676 to Anapliotis (hereinafter "the Anapliotis patent"). The Anapliotis patent does not disclose the subject matter of the amended claims.

The Anapliotis patent does not disclose the subject matter of the amended claims. The Examiner asserts that Anapliotis discloses "a generally tubular elastic nonwoven," citing Col. 1, lines 51-54, and col. 4, lines 33-37. (See Examiner's 22 February 2006 Final Office Action at pp. 3-4). A reader, directed to the first citation, finds the following: "The apparatus according to the preferred embodiment of the invention includes slip-on, elastic protective clothing article for measuring the pH of vaginal fluid during gynecological examinations." Directed to the second citation, one finds the following: "The protective clothing article 10 is preferably made of polyethylene, since a particularly good adhesion is attainable with this material . . . ." Contrary to Examiner's assertion, the cited language does not disclose a generally tubular elastic nonwoven. (See present application at page 6,

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line 16 et seq., in which a nonwoven web is defined as "a web having a structure of individual fibers or threads that are interlaid, but not in an identifiable manner as in a knitted fabric.) A search of an electronic document corresponding to US 6,123,676 found on the MicroPatent database for the term "nonwoven" was unsuccessful (i.e., using the "Find" feature, the term "nonwoven" was not found in the electronic document). Because Anaplliotis does not disclose each and every element of the claimed invention, it cannot anticipate.

In view of the remarks set forth in this section, Applicants respectfully submit that claims 41, 43, 51, 53, 56, 57, 75, 77, and 79 are in condition for allowance and respectfully request favorable consideration and the timely allowance of those claims.

4. Rejection of Claim 79 Under 35 U.S.C. §102(b). In the Office Action mailed 22 February 2006, the Examiner rejected claim 79 as being unpatentable under 35 U.S.C. §102(b) over U.S. Patent No. 3,672,351 to Ubersax (hereinafter "the Ubersax patent").

Claim 79, as amended, is directed to a device that includes a generally tubular body that includes a first and second panel, each panel comprising a nonwoven material (in one panel the nonwoven material is elastic). To anticipate, a reference must disclose each and every element of the claimed invention. Nowhere does Ubersax disclose a generally tubular body that includes the recited nonwoven panels. Ubersax discloses a "glove of an impermeable material" such as "rubber or other elastic or plastic material" that has a test patch affixed to it, with the patch made of "paper, cloth, felt, or other bibulous material." (See col. 1, lines 29-35.) Because Ubersax does not disclose each and every element of the claimed invention, it does not anticipate, and the rejection should be withdrawn.

5. Rejection of Claim 78 Under 35 U.S.C. §102(b). In the Office Action mailed 22 February 2006, the Examiner rejected claim 78 as being unpatentable under 35 U.S.C. §102(b) over U.S. Patent No. 4,335,731 to Bora (hereinafter "the Bora patent").

Claim 78, as amended, is directed to a device that includes a generally tubular body that includes a first and second panel, each panel comprising a nonwoven material (in one panel the nonwoven material is elastic). To anticipate, a reference must disclose each and every element of the claimed invention. Nowhere does Bora disclose a generally tubular body that includes the recited nonwoven panels. Again the Examiner points to language in the document that purportedly disclose the claimed invention(s). But a reader finds no such disclosure. At column 3, lines 20-30, which the Examiner characterizes as disclosing a "nonwoven web" and an "elastic nonwoven material," one finds the following: "As shown in Fig. 4a, an alternate device for this category of dental wipes for cleaning teeth is a finger cott 32 which has a "U" shaped sheet 34 and sheet 36 which are secured together at their edges as by heat seeling with a sheet 38 between them to form a finger stall for the reception of an index finger. The sheets 34 and 36 are flexible reticulated polyurethane foam or flexible non-

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reticulated polyurethane foam or a combination of both. Sheet 38 is substantially firmer than sheets 36 and 38 and of, for example, a firm polymeric material." Because Bora does not disclose each and every element of the claimed invention, it does not anticipate, and the rejection should be withdrawn.

6. Rejection of Claims 41, 43, 46, 48 and 76 Under 35 U.S.C. §103(a). In the Office Action mailed 22 February 2006, the Examiner rejected the preceding claims as unpatentable over U.S. Patent Application Publication Number 2004/0092843 to Kreiser et al. ("Kreiser") in view of U.S. Patent No. 5,728,340 to Dreibelbis et al. ("Dreibelbis").

Kreiser is generally directed to a glove or finger cot, attached to which is a lancet for incising the scalp of a fetus. (See Abstract.) Dreibelbis is generally directed to a process for making thin-wall articles such as gloves or condoms from a solution of polyesterurethaneurea in an organic solvent. (See, e.g., col. 2, lines 19-22.) From this combination, the Examiner concludes that the claimed invention, which is generally directed to methods implicating use of a device that includes a generally tubular body having a nonwoven construction, is obvious. We respectfully disagree. Nowhere do the cited references, either individually, or in combination, teach or suggest a device employing nonwoven materials for use in methods such as those claimed here. Accordingly, we respectfully request that the rejection be withdrawn and the claims allowed.

7. Rejection of Claims 44, 45, 54, and 55 as Obvious. In the Office Action mailed 22 February 2006, the Examiner rejected claims 44, 45, 54, and 55 as being unpatentable under 35 U.S.C. §103(a) over the Anapliotis patent in view of U.S. Patent No. 6,114,024 to Forte ("the Forte patent").

Anapliotis is discussed above at Argument #3. It is generally directed to a "slip-on, elastic protective clothing article for measuring the pH of vaginal fluid during gynecological examinations." "The protective clothing article 10 is preferably made of polyethylene, since a particularly good adhesion is attainable with this material . . . ." (See citations at Argument #3.) Forte is generally directed to a breathable film. (See Abstract.) From this combination, the Examiner concludes that the claimed invention, which is generally directed to methods implicating use of a device that includes a generally tubular body having a nonwoven construction, is obvious. We respectfully disagree. Nowhere do the cited references, either individually, or in combination, teach or suggest a device employing nonwoven materials for use in methods such as those claimed here. Accordingly, we respectfully request that the rejection be withdrawn and the claims allowed.

8. Rejection of Claims 49 and 50 as Obvious. In the Office Action mailed 22 February 2006, the Examiner rejected the preceding claims as unpatentable over U.S. Patent Application Publication Number 2004/0092843 to Kreiser et al. ("Kreiser") in view of U.S. Patent No. 5,728,340 to Dreibelbis et

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al. ("Dreibelbis") and further in view of U.S. Patent No. 6,114,024 to Forte ("the Forte patent").

Kreiser, Dreibelbis, and Forte have all been discussed above. None of these references disclose literally, nor do they teach or suggest, methods implicating a device that includes a generally tubular body employing nonwoven materials in the construction of said body. Examiner appears to repeatedly mistake the presence of a film, impermeable layer, or specific long-chain polymers (e.g., polyethylene) as equating to a nonwoven material (again, this is defined for purposes of the present application as "a web having a structure of individual fibers or threads that are interlaid, but not in an identifiable manner as in a knitted fabric.") Accordingly, we respectfully request that the rejection be withdrawn and the claims allowed.

**9. Rejection of Claim 58 as Obvious.** In the Office Action mailed 22 February 2006, the Examiner rejects claim 58 as being unpatentable under 35 U.S.C. §103(a) over the Anaplotis patent in view of U.S. Patent No. 5,660,790 to Lawrence et al. ("the Lawrence patent"). Applicants respectfully traverse the rejection.

Anaplotis is discussed above (see, e.g., Argument #7 above). Lawrence discloses pH test devices, which are generally depicted as flat, placard-like devices (See Abstract and Figures.) From these disclosures, the Examiner asserts that the claimed invention is obvious. None of these references disclose literally, nor do they teach or suggest, methods implicating a device that includes a generally tubular body employing nonwoven materials in the construction of said body. Accordingly, we respectfully request that the rejection be withdrawn and the claims allowed.

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#### Conclusion

For the reasons stated above it is Appellants' position that the Examiner's rejection of claims has been shown to be untenable and should be reversed by the Board.

Please charge the \$500.00 fee (fee code 1402), pursuant to 37 C.F.R. 41.20(b)(2), for filing this Appeal Brief to Kimberly-Clark Worldwide, Inc. deposit account number 11-0875. Any additional prosecutorial fees which are due may also be charged to deposit account number 11-0875.

The undersigned may be reached at: (920) 721-2747

Respectfully submitted,

ROSANN MARIE MATTHEWS KAYLOR ET AL.

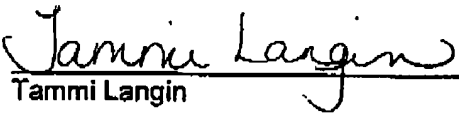
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Sebastian C. Pugliese III  
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**CERTIFICATE OF TRANSMISSION**

I, Tammi Langin, hereby certify that on February 20, 2007 this document is being facsimile transmitted to the United States Patent and Trademark Office, Fax No. (571) 273-8300.

  
\_\_\_\_\_  
Tammi Langin

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**Appendix – The Claims On Appeal**

The claims on appeal are:

1. (Withdrawn) A device for capturing a substance, the device comprising:  
a generally tubular body including  
a generally tubular inner surface defined by a first layer, the inner surface defining a pocket therewithin, the pocket having a distal end and a proximal end, the distal end being generally closed and the proximal end being generally open, the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end, and  
a generally tubular outer surface generally disposed radially outwardly from the inner surface, wherein a portion of the outer surface is adapted to capture the substance.
2. (Withdrawn) The device of claim 1, wherein the first layer includes a barrier material.
3. (Withdrawn) The device of claim 2, wherein the barrier material is breathable to water vapor.
4. (Withdrawn) The device of claim 1, further comprising a second layer coupled to the first layer.
5. (Withdrawn) The device of claim 4, wherein the second layer includes at least two layers of material such that the second layer constitutes a laminate.
6. (Withdrawn) The device of claim 4, wherein the second layer includes a nonwoven material.
7. (Withdrawn) The device of claim 6, wherein the nonwoven material is a thermoplastic material.
8. (Withdrawn) The device of claim 6, wherein the nonwoven material is a polypropylene material.
9. (Withdrawn) The device of claim 6, wherein the nonwoven material is a hydrophobic material.

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10. (Withdrawn) The device of claim 6, wherein the nonwoven material is a hydrophilic material.
11. (Withdrawn) The device of claim 6, wherein the nonwoven material is a mixture of hydrophobic and hydrophilic materials.
12. (Withdrawn) The device of claim 6, wherein the nonwoven material is selected from the group consisting of spunbonded fiber materials, meltblown fiber materials, spunbonded/meltblown/spunbonded fiber materials, spunbonded/meltblown fiber materials, coform, and bonded carded materials.
13. (Withdrawn) The device of claim 6, wherein the nonwoven material comprises an elastic component.
14. (Withdrawn) The device of claim 13, wherein the elastic component includes a fibrous material.
15. (Withdrawn) The device of claim 13, wherein the elastic component includes a film.
16. (Withdrawn) The device of claim 1, wherein the portion is adapted to retain the substance.
17. (Withdrawn) The device of claim 1, wherein the portion is adapted to release the substance.
18. (Withdrawn) The device of claim 1, wherein the portion is adapted to release the substance to a biosensor for testing.
19. (Withdrawn) The device of claim 1, wherein the substance is an indicator agent.
20. (Withdrawn) The device of claim 19, further comprising a second portion of the outer surface adapted to capture a second substance.
21. (Withdrawn) The device of claim 20, wherein the second substance is a second indicator agent.

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22. (Withdrawn) The device of claim 20, wherein the second substance is a beneficial agent.
23. (Withdrawn) The device of claim 19, wherein the portion is adapted to deposit the indicator agent on a test subject.
24. (Withdrawn) The device of claim 23, wherein the test subject is associated with a body.
25. (Withdrawn) The device of claim 19, wherein the indicator agent is adapted to indicate pH.
26. (Withdrawn) The device of claim 25, wherein the pH indication is used to detect premature rupture of membrane.
27. (Withdrawn) The device of claim 25, wherein the pH indication is used to detect bacterial or trichomonal vaginal infections.
28. (Withdrawn) The device of claim 19, wherein the indicator agent is selected from the group consisting of: methyl red, bromothymol blue, nitrazine, sulfanilamide compounds with acidic buffers, diazonium salts with acidic buffers, glucose oxidase / peroxidase, indoxylcarbonic acid ester modified with a diazonium salt, dichlorobenzene diazonium tetrafluoroborate, tetramethylbenzidine in the presence of peroxide, and methoxybenzene diazonium tetrafluoroborate.
29. (Withdrawn) The device of claim 1, further comprising an elastic component.
30. (Withdrawn) The device of claim 29, wherein the elastic component includes a fibrous material.
31. (Withdrawn) The device of claim 29, wherein the elastic component includes a film.
32. (Withdrawn) The device of claim 1, wherein the barrier material includes a moisture barrier, the moisture barrier being substantially impermeable to liquids when contacted therewith.
33. (Withdrawn) The device of claim 32, wherein the moisture barrier comprises a plastic film.
34. (Withdrawn) The device of claim 33, wherein the plastic film is a microporous film.

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35. (Withdrawn) The device of claim 32, wherein the moisture barrier comprises a multi-layered laminate.

36. (Withdrawn) The device of claim 35, wherein one of the layers of the moisture barrier comprises a nonwoven web of fibrous material.

37. (Withdrawn) The device of claim 35, wherein one of the layers of the moisture barrier comprises a vapor-permeable film.

38. (Withdrawn) The device of claim 1, wherein the substance is selected from the group consisting of: saliva, mucous, lung-based sputum, oral plaque, nasal fluid, tears, ear wax, vaginal fluid, cervical fluid, menses, seminal fluid, urine, blood, feces, sweat, skin oils, skin cells, scalp debris, cerebrospinal fluid, amniotic fluid, synovial fluid, serous fluid, and bronchial washings.

39. (Withdrawn) The device of claim 1, wherein the substance is a beneficial agent, and wherein a portion of the device is adapted to deposit the beneficial agent on a test subject.

40. (Withdrawn) The device of claim 39, wherein the beneficial agent is selected from the group consisting of: medicaments, diaper rash ointments, alcohols, anesthetics, analgesics, facial make-up removal agents, anti-microbials, antibacterials, baking powder, moisturizing agents, lubricants, vitamins, and nutrients.

41. (Currently amended) A method for collecting a sample from a test subject, the method comprising:

providing a device adapted to capture and retain the sample, wherein the device includes a generally tubular nonwoven body including a generally tubular inner surface defined by an interior layer, the inner surface defining a pocket therewithin, the pocket having a distal end and a proximal end, the distal end being generally closed and the proximal end being generally open, the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end, and a generally tubular outer surface;

inserting a finger into the pocket; and  
contacting the sample with the device.

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42. (Withdrawn) The method of claim 41, further comprising:

providing a second device adapted to capture and release an agent, wherein the device includes a generally tubular body including a generally tubular inner surface defined by an interior layer, the inner surface defining a pocket therewithin, the pocket having a distal end and a proximal end, the distal end being generally closed and the proximal end being generally open, the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end, and a generally tubular outer surface;

inserting a finger into the pocket; and

contacting the sample with the second device such that the agent is released.

43. (Original) The method of claim 41, wherein the contacting act includes contacting a sample selected from the group consisting of: saliva, mucous, lung-based sputum, oral plaque, nasal fluid, tears, ear wax, vaginal fluid, cervical fluid, menses, seminal fluid, urine, blood, feces, sweat, skin oils, skin cells, scalp debris, cerebrospinal fluid, amniotic fluid, synovial fluid, serous fluid, and bronchial washings.

44. (Original) The method of claim 41, wherein the providing act includes providing a device with an interior layer including a barrier material, and wherein the barrier material is breathable to water vapor.

45. (Original) The method of claim 44, wherein the barrier material includes a moisture barrier, the moisture barrier being substantially impermeable to liquids when contacted therewith.

46. (Previously amended) A method for analyzing a sample, the method comprising:

providing a device adapted to capture and retain the sample, wherein the device includes a generally tubular nonwoven body including a generally tubular inner surface defined by an interior layer, the inner surface defining a pocket therewithin, the pocket having a distal end and a proximal end, the distal end being generally closed and the proximal end being generally open, the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end, and a generally tubular outer surface;

contacting the substance to be sampled with the device; and

analyzing the device using a reader.

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47. (Withdrawn) The method of claim 46, further comprising:

providing a second device adapted to capture and release an agent, wherein the device includes a generally tubular body including a generally tubular inner surface defined by an interior layer, the inner surface defining a pocket therewithin, the pocket having a distal end and a proximal end, the distal end being generally closed and the proximal end being generally open, the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end, and a generally tubular outer surface;

inserting a finger into the pocket; and

contacting the test subject with the second device such that the agent is released.

48. (Original) The method of claim 46, wherein the contacting act includes contacting a substance selected from the group consisting of: saliva, mucous, lung-based sputum, oral plaque, nasal fluid, tears, ear wax, vaginal fluid, cervical fluid, menses, seminal fluid, urine, blood, feces, sweat, skin oils, skin cells, scalp debris, cerebrospinal fluid, amniotic fluid, synovial fluid, serous fluid, and bronchial washings.

49. (Original) The method of claim 46, wherein the providing act includes providing a device with an interior layer including a barrier material, and wherein the barrier material is breathable to water vapor.

50. (Original) The method of claim 49, wherein the barrier material includes a moisture barrier, the moisture barrier being substantially impermeable to liquids when contacted therewith.

51. (Previously amended) A method for analyzing a sample, the method comprising:

providing a device adapted to capture and retain the sample, wherein the device includes a generally tubular nonwoven body including a generally tubular inner surface defined by an interior layer, the inner surface defining a pocket therewithin, the pocket having a distal end and a proximal end, the distal end being generally closed and the proximal end being generally open, the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end, and a generally tubular outer surface including an indicator agent;

contacting the substance to be sampled with the device; and

observing the reaction of the sample with the indicator agent on the device.

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52. (Withdrawn) The method of claim 51, further comprising:

providing a second device adapted to capture and release an agent, wherein the device includes a generally tubular body including a generally tubular inner surface defined by an interior layer, the inner surface defining a pocket therewithin, the pocket having a distal end and a proximal end, the distal end being generally closed and the proximal end being generally open, the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end, and a generally tubular outer surface;

inserting a finger into the pocket; and

contacting the test subject with the second device such that the agent is released.

53. (Original) The method of claim 51, wherein the contacting act includes contacting a substance selected from the group consisting of: saliva, mucous, lung-based sputum, oral plaque, nasal fluid, tears, ear wax, vaginal fluid, cervical fluid, menses, seminal fluid, urine, blood, feces, sweat, skin oils, skin cells, scalp debris, cerebrospinal fluid, amniotic fluid, synovial fluid, serous fluid, and bronchial washings.

54. (Original) The method of claim 51, wherein the providing act includes providing a device with an interior layer including a barrier material, and wherein the barrier material is breathable to water vapor.

55. (Original) The method of claim 54, wherein the barrier material includes a moisture barrier, the moisture barrier being substantially impermeable to liquids when contacted therewith.

56. (Original) The method of claim 51, wherein the observing act includes observing the reaction without electromechanical assistance.

57. (Original) The method of claim 51, wherein the observing act includes observing the reaction with the aid of a light source.

58. (Original) The method of claim 51, wherein the observing act includes observing the reaction using a reader.



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59. (Withdrawn) A method for analyzing a test subject, the method comprising:

providing a device adapted to capture and release an indicator agent, wherein the device includes a generally tubular body including a generally tubular inner surface defined by an interior layer, the inner surface defining a pocket therewithin, the pocket having a distal end and a proximal end, the distal end being generally closed and the proximal end being generally open, the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end, and a generally tubular outer surface including the indicator agent;

contacting the test subject to be analyzed with the device, such that at least a portion of the indicator agent is released to the test subject; and

observing the reaction of the test subject with the indicator agent.

60. (Withdrawn) The method of claim 59, further comprising:

providing a second device adapted to capture and release an agent, wherein the device includes a generally tubular body including a generally tubular inner surface defined by an interior layer, the inner surface defining a pocket therewithin, the pocket having a distal end and a proximal end, the distal end being generally closed and the proximal end being generally open, the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end, and a generally tubular outer surface;

inserting a finger into the pocket; and

contacting the test subject with the second device such that the agent is released.

61. (Withdrawn) The method of claim 59, wherein the providing act includes providing a device with an interior layer including a barrier material, and wherein the barrier material is breathable to water vapor.

62. (Withdrawn) The method of claim 61, wherein the barrier material includes a moisture barrier, the moisture barrier being substantially impermeable to liquids when contacted therewith.

63. (Withdrawn) The method of claim 61, wherein the observing act includes observing the reaction without electromechanical assistance.

64. (Withdrawn) The method of claim 61, wherein the observing act includes observing the reaction with the aid of a light source.

65. (Withdrawn) The method of claim 61, wherein the observing act includes observing the reaction using a reader.

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66. (Withdrawn) A method for applying a substance to a test subject, the method comprising:

providing a device adapted to capture and release the substance, wherein the device includes a generally tubular body including a generally tubular inner surface defined by an interior layer, the inner surface defining a pocket therewithin, the pocket having a distal end and a proximal end, the distal end being generally closed and the proximal end being generally open, the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end, and a generally tubular outer surface, wherein the outer surface includes the substance;

contacting the test subject with the device such that at least a portion of the substance is released from the device and deposited on the test subject.

67. (Withdrawn) The method of claim 66, wherein the providing act includes providing an indicator agent.

68. (Withdrawn) The method of claim 67, wherein the indicator agent is selected from the group consisting of: methyl red, bromothymol blue, nitrazine, sulfanilamide compounds with acidic buffers, diazonium salts with acidic buffers, glucose oxidase / peroxidase, indoxylcarbonic acid ester modified with a diazonium salt, dichlorobenzene diazonium tetrafluoroborate, tetramethylbenzidine in the presence of peroxide, and methoxybenzene diazonium tetrafluoroborate.

69. (Withdrawn) The method of claim 66, wherein the providing act includes providing a beneficial agent.

70. (Withdrawn) The method of claim 69, wherein the beneficial agent is selected from the group consisting of: medicaments, diaper rash ointments, alcohols, anesthetics, analgesics, facial make-up removal agents, anti-microbials, antibacterials, baking powder, moisturizing agents, lubricants, vitamins, and nutrients.

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71. (Withdrawn) A device for capturing a substance, the device comprising:

a generally tubular body including

a generally tubular inner surface defined by a first layer, the first layer, wherein the barrier material includes a moisture barrier that is substantially impermeable to liquids when contacted therewith, the inner surface defining a pocket therewithin, the pocket having a distal end and a proximal end, the distal end being generally closed and the proximal end being generally open, the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end, and

a generally tubular outer surface generally disposed radially outwardly from the inner surface, wherein a portion of the outer surface is adapted to capture the substance.

72. (Withdrawn) A diagnostic kit comprising:

a collection device including a generally tubular body, the body including

a generally tubular inner surface defined by a first layer, the inner surface defining a pocket therewithin, the pocket having a distal end and a proximal end, the distal end being generally closed and the proximal end being generally open, the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end, and

a generally tubular outer surface generally disposed radially outwardly from the inner surface, wherein a portion of the outer surface is adapted to capture the substance; and

an indicator device adapted to generate a diagnosis using the substance from the collection device.

73. (Withdrawn) A sample collection system comprising:

a first collection device to collect a first substance, wherein the first collection device includes a generally tubular body, the body including

a generally tubular inner surface defined by a first layer, the inner surface defining a pocket therewithin, the pocket having a distal end and a proximal end, the distal end being generally closed and the proximal end being generally open, the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end, and

a generally tubular outer surface generally disposed radially outwardly from the inner surface, wherein a portion of the outer surface is adapted to capture the substance; and

a second collection device to collect a second substance.

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74. (Withdrawn) A sample collection system comprising:

a first a collection device including a generally tubular body, the body including  
a generally tubular inner surface defined by a first layer, the inner surface defining a pocket therewithin, the pocket having a distal end and a proximal end, the distal end being generally closed and the proximal end being generally open, the proximal end being configured to allow the insertion of a finger into the pocket through the proximal end, and  
a generally tubular outer surface generally disposed radially outwardly from the inner surface, wherein a portion of the outer surface is adapted to capture the substance; and  
a second collection device larger than the first collection device.

75. (Previously presented) The method of claim 41, wherein the providing act includes providing a device wherein the body comprises an elastic nonwoven material.

76. (Previously presented) The method of claim 46, wherein the providing act includes providing a device wherein the body comprises an elastic nonwoven material.

77. (Previously presented) The method of claim 51, wherein the providing act includes providing a device wherein the body comprises an elastic nonwoven material.

78. (Previously presented) A method for collecting a sample from a test subject, the method comprising:

providing a finger glove device adapted to capture and retain the sample, wherein the finger glove device includes a generally tubular body including an open end for the insertion of a finger, the body comprising a first panel thermally bonded to a second panel thereby forming a seam, the first panel comprising a non-elastic material containing a nonwoven web, the second panel comprising an elastic nonwoven material, the elastic nonwoven material being capable of being stretched and contracted for providing the finger glove device with form fitting properties;

inserting a finger into the open end; and

contacting the sample with the finger glove device.

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79. (Previously presented) A method for analyzing a sample, the method comprising:  
providing a device adapted to capture and retain the sample, wherein the device includes a generally tubular body including a first panel attached to a second panel, the first panel and the second panel defining a pocket therebetween, the pocket having a distal end and a proximal end, the distal end being closed, the proximal end being open and configured to allow the insertion of a finger into the pocket, the second panel comprising an elastic nonwoven material, wherein the device has a generally tubular outer surface including an indicator agent;  
contacting the substance to be sampled with the device; and  
observing the reaction of the sample with the indicator agent on the device.

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**Evidence Appendix**

None.

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**Related Proceedings Appendix**

None.